Applicant(s) : Ivan C. KING, and Li Mou ZHENG
U.S. Serial No.: 10/738,423
Filed : 12/16/2003
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Remarks

Claims 100-112 are pending.

Claims 101, 102, 104, 105, 107, 109-110 have been canceled without prejudice. Applicant reserves the right to rejoin the canceled subject matter upon allowance of a generic claim.

Claims 100, 103, 106, 108, 111-112 have been amended as indicated above. Support for the amendment can be found in the last paragraph of page 32 of the specification.

No amendment is believed to add new matter.

Examiner's comments are addressed in sequence below.

Priority

Examiner has indicated that the priority date for the instant application is 12/16/2003, i.e., the filing date and not October 4, 1999 as detailed in the specification. The basis for Examiner's determination is that the priority applications, 09/645,415 and the preceding provisional applications, allegedly fail to provide adequate support or enablement for attenuated tumor-targeted bacteria lacking a nucleic acid encoding a primary effector molecule. Applicant respectfully disagrees.

Example 28 in priority application USSN 09/645,415, now US Patent 6,962,696, fully describes and enables the use of attenuated strains of Salmonella that do not further comprise one or more effector-molecule encoding nucleic acids.

Accordingly, the correct priority date under 119(e) is October 4, 1999. Applicant respectfully requests that the next office

communication affirmatively state whether or not the status of the originally supplied priority dates under 119(e) and 120 have been restored.

Rejections Under 112,2nd Paragraph

Claims 100, 103, 106, 108, 111 and 112 are rejected for allegedly being vague and indefinite. Examiner asserts that the specification does not define what structure is required to meet the claim limitations, particularly, tumor targeting.

In response, Examiner's attention is respectfully directed to each of the last paragraphs on pages 20 and 22 of the specification, wherein the definitions of *attenuated* and *tumor-targeting*, respectively, are provided. As set forth in MPEP 2173.02,

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

(Emphases added).

It is respectfully suggested that the claims clearly meet the "reasonable degree" requirement even without further reference to the specification. Therefore, in view of the cited definitions on pages 20 and 22, it is suggested that persons of ordinary skill in the art would have no problem appreciating the metes and bounds of the

claimed subject matter based on the claim language alone, or read in context with the specification.

Rejections Under 112, 1st Paragraph

The Examiner rejected claims 100, 103,106,111 and 112 under 35 U.S.C. 112, first paragraph, for allegedly not being fully enabled by the specification.

Although not conceding the validity of the rejection, Applicants have amended the claims to conform with Examiner's comments solely to expedite the prosecution to completion. It is believed that the amended claims can be practiced to the fullest extent of their scope without undue experimentation. It is respectfully submitted that this conclusion is further supported by the very high level of skill in the art.

Accordingly, it is respectfully requested that the rejection be withdrawn.

Rejection Under 103(a)

Claims 100, 103,106, 108,111 and 112 are rejected for allegedly being obvious over Low et al., and Schachter et al. Applicant respectfully disagrees that these references taken individually or in combination are sufficient to teach or suggest the claimed subject matter.

As indicated in Low et al., the diminished virulence of the bacteria is partially based upon the loss of TNF-α induction. In contrast, Schachter's therapy is predicated on increasing certain cytokine levels (IFN-α and GM-CSF) in melanoma patients. Although the cytokines involved are not identical, it appears that the *in vivo* conditions that Schachter teaches as being required for effective

therapy would be detrimental to the approach of employing the attenuated bacterial vectors of the claimed method.

Accordingly, it would not be apparent how this combination of references would lead persons of ordinary skill in the art to the claimed subject matter. "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." MPEP 2143.01, *citing* In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

In fact, the Schachter's method may actually provide a subject with an internal milieu in which the claimed method could not be practiced effectively. This is sufficient to demonstrate that combining Low and Schachter does not reach a prima facie case of obviousness. See MPEP 2143.01. (If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).)

It is respectfully suggested that a *prima facie* case of obviousness has not been set forth in this office action. In accordance, withdrawal of the rejection under § 103(a) is respectfully requested.

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If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

I hereby certify that this paper is being facsimile-transmitted to:

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on the date shown below.

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